

# **PRIVACY, PROPERTY OR PERMISSION? NEED OUR MODELS FOR REGULATING PERSONAL GENETIC MATERIAL BE MUTUALLY EXCLUSIVE?**

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## **ABSTRACT**

An argument is favor of extending property protection to individuals in respect of their genetic materials and information derived from those materials.

## **KEY WORDS**

Privacy, genetic material, self-ownership, consent

## **1. INTRODUCTION**

This paper builds on my earlier work which examines privacy issues relating to genetic material and information derived from that material.[1] In that work I have argued that a more robust concept of privacy is required than is currently available to allow us to meet to challenges posed by increased availability of genetic information. I have posited that existing medico-legal paradigms, such as respect for individual autonomy and protection of patient confidentiality, do not provide adequate protection of the range of interests that individuals might have in their genetic constitution. Accordingly, I have proposed a new model of privacy protection that seeks to complete the family of values that I believe should work in parallel to provide such protection.

However, although I am generally ‘pro-privacy’, I also recognize the limitations of privacy, both in theory and in practice. One such limitation is that a privacy right - however conceived - is always a right of non-interference. It does not constitute a right of positive entitlement. To this extent, privacy suffers from limitations similar to those that afflict the principle of respect for autonomy, namely, it does not provide for any *continuing control* over personal matters once they enter the public sphere. Autonomy in the guise of consent reduces control to the giving or withholding of that consent after which an individual is largely powerless to dictate what happens.[2] Thus, for example, while an individual might consent to make private information public, she will have no continuing control over what is then done with her data. Similarly, if an individual consents to provide tissue samples for research purposes she loses control of those samples for all time coming. She is not in a position to dictate the fate of the samples by exercising her right to privacy. And, while her privacy in any information derived from those samples may continue to be protected, any residual authority depends on the nature of her original consent and, more importantly, on the assumption that its terms will not be violated.

Privacy and autonomy are, therefore, of limited utility. They are, however, unified at the fundamental level by the fact that each reflects a valued aspect of the human personality.[3] If, however, we find them inadequate guardians of 'self', we should explore other options - as yet largely uncharted - that may give fuller protection to interests in the persona. This paper does so by considering the role of property in this regard.

## **2. BODY OF PAPER**

German law protects the body as an aspect of the right to personality. If interference occurs with excised parts of the body - such as the unauthorised destruction of sperm - the law will provide a remedy for a breach of the *Persönlichkeitsrecht*. [4] The way this is done is by recognizing enforceable property rights in excised human material. [5] Anglo-American law is less sophisticated in this regard. Our tendency has been to treat privacy and autonomy as one branch of protection, and property as another. Numerous examples can be given. Most notable is the experience in Oregon, where the state took the bold step in 1995 of embodying a personal property right in genetic information and DNA samples when used for anonymous research with the result that that unauthorised interference with either constituted an actionable tort. [6]

However, after several years of lobbying by the pharmaceutical industry and research institutes, a new Bill was passed in June 2001 that removed this right and replaced it with more stringent privacy protection. [7] The claim is that Oregon now has the most far-reaching privacy legislation of its kind in the United States. The reality is that the two concepts of privacy and property are treated as 'either/or' options when there is no sound reason to do so. The Oregon experiment was not given sufficient time for the promise and the pitfalls of a property paradigm to be explored and addressed. In the UK, the Human Genetics Commission [8] has recently issued its recommendations on protecting personal genetic data, but it too has eschewed the property paradigm in favor of an approach couched in the traditional concepts of 'more and better consent', and 'adequate protection of privacy interests'. [9] This would not be so objectionable but for the fact that property rights *are* granted over human material. This happens all the time, and is actively encouraged by governments around the world. It happens, of course, through the mechanisms of intellectual property law, and primarily through the granting of patents. But the property owners in such cases, as the infamous *Moore* case demonstrated only too well, [10] are the 'inventors' - i.e. the researchers, and not the subjects from whom the material was derived.

Much has been written about the inequities of this, and it has even prompted the Human Genome Organization's Ethics Committee admirably to recommend that: 'profit-making entities dedicate a percentage (e.g 1-3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts'. [11] However, in this short paper I would like to propose an alternative strategy: recognition of property rights in ourselves.

### **The need for an additional approach?**

One might ask why is such a strategy needed? A number of points can be made. There is, for example, an undeniable public crisis of confidence in genetic research, even though its promise

is well recognised. This is borne out by the UK Medical Research Council's survey into public perceptions of the collection of human biological samples - published in October 2000.[12] This general atmosphere of mistrust is compounded in large part by the increased role that the private sector has assumed in undertaking, financing and staking a claim to research involving human genetic material. The granting of intellectual property rights over the products of this research has served only to alienate the public even further. These issues will not be addressed adequately just by the simple removal of intellectual property protection from the equation. Pragmatically, this is not even a viable option, but more importantly the very strong public interest in encouraging innovation would be lost to any state or geographical area that attempted to use it; the research and innovation that biotechnology attracts would simply move elsewhere. The real problem is two-fold. First, where should the proper focus lie in addressing this crisis of confidence? Second, what role, if any, should law play in that process?

The reality is that those who participate as subjects and who provide vital genetic research material are the key components of the genetic research machine and are crucial to its continued success. Whether they are represented by individuals or by communities, they are currently undervalued, under respected and undermined. The way forward is to empower these parties to take a more equal role in the partnership that is formed when they participate in research.[13] The starting point is to break free of current institutional constraints that stand in the way of this progress and to explore more imaginative ways by which we can establish, and perhaps protect, the role of those who further the *public* interest in genetic research.

Maybe so, but why property? Well, the exclusion of individuals from the human property model, when this model is available to others, has been strongly objected to by many who advocate a more consistent application of the law.[14] This in turn is part of a wider movement that involves a re-assessment of the relationship that individuals enjoy with their own bodies and the legal rights that can be claimed in respect of that relationship.[15]

Moreover, current models are inadequate to redress imbalances. The conflation of autonomy with consent that is typical of current approaches to medico-legal dilemmas reduces the means of respecting individuals to one solitary event - the obtaining of informed consent. And, while numerous ways of maintaining respect for individuals are available when they remain passive in the process, the equiparation of autonomy with consent means that informed consent has come to be the primary, and for many the only, legitimate way of *empowering* individuals in their dealings with health care professionals and researchers. This is also true in the spheres of intellectual property and biotechnology. But this need not and should not be so. Two examples illustrate the current approach.

When the European Patent Office's Opposition Division was called upon in 1994 to examine the morality of Howard Florey's patent over the H2-Relaxin - a protein secreted by pregnant woman that eases the process of childbirth - it did so in large part by reference to the principle of informed consent.[16] It had been objected, *inter alia*, that the granting of the patent offended morality because it required the removal of tissue from pregnant women; this was said to be an affront to human dignity because it used a particular female condition (pregnancy) for a technical process oriented towards profit. The answer of the Opposition Division, however, was that the

tissue had been freely donated by the women in question, and that, therefore, the manipulation of genetic material from those samples was not immoral.[17]

Second, Recital 26 of the European Directive on the legal protection of biotechnological inventions provides that: ‘Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law’.[18]

The terms of Recital 26 were originally intended for inclusion as an Article of the Directive with clear binding force on member states, but heavy lobbying by representatives of the biotechnology and patent industries meant that it was ultimately relegated to the Preamble to the Directive, where its legal status and its effect on member states is far less certain.[19]

None the less, such formulations of consent certainly provide adequate protection for the researchers. They also represents one means of respecting individuals. Indeed, they are highly desirable safeguards. However, they are considerably less successful as a means of empowering individuals. And, it is precisely because people feel disenfranchised from, and disempowered by, the modern machinery of research that we face the current public crisis of confidence in research in general and genetic research in particular. Individuals who provide samples for research purposes are not, and do not feel like, stake-holders in the enterprise. The continued participation and support of the public in research activity can only be ensured by a fundamental reappraisal of the relationships with the subjects that have traditionally been accepted.

The imperative to seek and obtain consent from research subjects gives them an illusion of power and control. In reality, it delegates extremely limited control to individuals. The sole power that is afforded is that to withhold consent - that is, to refuse. Moreover, there is no residual power once consent has been given unless further consent is required at some future point. This is demonstrated particularly well in the context of the donation of samples for research. The focus on consent renders the participatory process disempowering in at least two senses: (i) for those who genuinely wish to participate in research the availability of a ‘right to refuse’ is useless; (ii) the one-off event of consent is disempowering because it fails to recognize the individual subject - or indeed, the community of research subjects - as a party with an interest in the overall endeavour. In sum, the fundamental problem with the consent model is that it does not provide a means by which the subjects can exercise *continuing control* of her materials.[20]

### **Revisiting the gift model**

This problem is compounded by the continuing use of the gift model to govern the researcher-subject relationship. The notion of gift has a strong normative appeal in lay terms, not least because it is seen to be a laudable act, demonstrating the virtues of altruism and beneficence, and untainted by the twin evils of self-interest or exploitation. In practice, it has considerable utility for the recipient, in that gifts for research purposes are treated as unconditional. This provides broad scope for the future use or disposal of the gift. As to public interest, unconditional gifting can serve a number of valuable social ends, including advances in medical research and the development of therapeutic agents or cures. This particular consideration weighs heavily as an

unquestionable given, but such a concept of gift is seriously incongruous in legal terms. In English law 'gift' is defined as 'the transfer of any *property* from one person to another gratuitously'[21] [emphasis added]

Thus, in legal terms the invocation of *gift* presupposes underlying property rights in the subject matter. As a result, the legal position in respect of ownership of donated human body parts is in disarray in most western legal systems.[22] A fair summation is that while there is no clear prohibition on ownership of body parts - and indeed, one can find many examples of a property model being applied to human tissues - the one player who is routinely excluded from the property model is the source of the property itself.[23]

The classic policy decision on self-ownership is to be found in the decision of the Supreme Court of California in *Moore v Regents of the University of California*,[24] in which the Californian Supreme Court denied the plaintiff any legal recognition of property rights in his own excised spleen cells. The court held that because no precedent could be found on which to ground Moore's property claim, and because of the utilitarian consideration that a finding for the plaintiff would be a hindrance to medical research 'by restricting access to the necessary raw materials',[25] it was inappropriate to recognise individual property rights in the body. Moreover, the Court was concerned that a contrary decision would '[threaten] to destroy the economic incentive to conduct important medical research' because '[i]f the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery'.[26] The paradox in this decision was highlighted by the dissent of Broussard, J. wherein he stated: '...the majority's analysis cannot rest on the broad proposition that a removed part is not property, but rather rests on the proposition that a *patient* retains no ownership interest in a body part once the body part has been removed from his or her body'.[27] Does it remain reasonable or defensible to exclude completely from the equation the one person who can make everything possible? More particularly, it is interesting to note how the court in *Moore* seemed entirely satisfied that its adoption of the consent model was sufficient to provide respect for, and to empower, the plaintiff (for Moore won in respect of lack of informed consent). The consent model and the property model were treated as though they were mutually exclusive; a phenomenon that has also been noted above in respect of property and privacy. There is, however, no sound reason why this should be so.

### **A property paradigm**

It is undeniable that an attitudinal shift is occurring in how we regard our bodies and parts removed from them.[28] Indeed, the MRC Working Group on Human Tissue and Biological Samples for Use in Research opined: '...it was more practical and more attractive from a moral and ethical standpoint to adopt the position that, if a tissue sample could be property, the original owner was the individual from whom it was taken'.[29]

It is submitted that there is nothing in principle to prevent recognition of property interests in aspects of the self, subject of course to limitations against self-harm. A personal property paradigm could, in fact, serve an all important role in completing the picture of adequate protection for the personality in tandem with other protections such as autonomy, confidentiality, and privacy.[30] However, the added value of a property model lies in its ability to empower

individuals and communities and to provide the crucial continuing control over samples or information through which on-going moral and legal influence may be exerted.

Property implies many things, including ownership and control. Property protection is, however, by no means an absolute, and as with all of our other legal rights, property rights can be tempered in our own interests or in those of others. Exercises of self-ownership therefore need not be recognized if these conflict with an individual's best interests. Examples include attempts to dispose of vital organs or tissues that would be detrimental to health. Nor should the law ever condone ownership of entire living human beings as this would be a fortiori impermissible as slavery. None the less, the recognition of property rights in excised body parts or samples does not carry any of these risks.

The reliance on the concept of gift in research culture presumes surrender of all residual interests in donated samples. However, not only does this lack support in law but it has also prompted the dual disservices of justifying a distorted gift paradigm while fuelling inconsistencies that ultimately undermine public confidence in research.[31]

It is no longer clear that the model of gifting currently employed in the modern research environment remains appropriate. It is not true, for example, that individuals retain no interest in materials surrendered for research. The moral significance of body parts remains even when they are separated from their original source. The MRC has found, for example, that: '[v]irtually everyone said that if they donated a sample they would appreciate feedback on what the research using their samples had discovered or achieved'.[32]

Nor should we ignore the fact that the commercial value that human material might represent to researchers also represents a potential value in those terms to the sample sources themselves. Not everyone agrees with the Supreme Court of California in *Moore*. [33] Numerous commentators point to principles of fundamental equity, the redress of unjust enrichment and the protection of personal interests that can be furthered through property rights.[34]

The recognition of this kind of interest in personal samples would provide the continuing control that is so lacking under the consent model alone.[35] Meaningful, legally relevant and enforceable conditions could be placed on any transfer of the property and so ensure that a research participant or indeed a community retains a vested interest in samples and in the goals and outcomes of any research for which those samples are provided. By the same token, restrictions on the inclusion of undesirable clauses by either side could easily be imposed by law.[36] It might be objected, for example, that property rights could easily be waived under pressure. The obvious retort to this is that no such assignation of rights should be legally permissible. Thus, while individuals or communities might choose not to exercise their rights, they could not simply give them away.

### **Current movements towards a property model**

Examples of communities working together can be found in North America where families have used their genetic uniqueness as a bargaining tool. Those suffering from the rare genetic disorder Pseudoxanthoma elasticum (PXE) have reached agreement with researchers only to provide samples on the condition that they are named as joint-patentees in any subsequent patent

applications, with a right to 50% of any proceeds.[37] This is an interesting reversal of fortune, for historically researchers would not take samples unless the consent included a grant of full title, even if this was meaningless in law. That such a bargain has been struck signals an important change in research culture, although the point remains that the property interests claimed by the families and their representatives may be unfounded in law. Fundamental principles of justice certainly support this approach,[38] but whether it could withstand serious legal analysis is open to debate.[39] Nevertheless, more such arrangements will undoubtedly be made.

At the time of writing a seminal case is proceeding through the American courts brought by parents of children affected by Canavan disease against researchers who developed and patented a test for the disorder using samples donated by the families. The defendants had worked closely with afflicted families receiving samples and gaining access to registers containing details of other affected groups around the world. However, when the Canavan gene was eventually identified the researchers sought a patent over it and a related test and proceeded to restrict access to the latter save through tightly controlled exclusive licenses. The plaintiffs objected strongly and have mounted an action on a number of grounds. These include, lack of informed consent, breach of fiduciary duty, and conversion. In this last respect, the plaintiffs claim a property interest in their samples, the genetic information therein and information contained in the Canavan Registry.

Paradoxically, this case stands in stark contrast to *Moore*, for here policy favors the plaintiffs. The families want information about the disease and the test to be freely available while it is the patent holders who wish to restrict access and so potentially hinder research. Policy will undoubtedly have a significant role to play in the outcome, but the policy arguments are strong on both sides,[40] and attitudes have moved on since *Moore* was decided in 1990.[41][42]

A cultural shift in attitude must, however, occur, as must a reassessment the nature of the relationship between researchers and subjects. I believe that these can be achieved in part through the discourse of property. We ought, then, to consider what it would mean to talk in terms of property rights in ourselves and how that language might be translated into law.

### **3. CONCLUSION: Defending a property model**

A number of counter-arguments can, however, be mounted. The concern that property rights in the self will hinder research held sway in *Moore* and lie at the core of the amendments to the Oregon law. However, it is far from established fact that research will be obstructed by furnishing sample sources with some small measure of bargaining power. Indeed, in the scheme of relative powers, those who provide the samples are at by far the greatest disadvantage. In most cases individuals would find that their property was of very little economic significance to researchers. But more positively, it has been suggested that research might be furthered rather than hindered by the recognition of property rights because those previously reluctant to come forward now have an incentive to do so.[43] Furthermore, the mere recognition of property does not preclude altruistic gifting.

The second major counter-argument is, of course, that commercialization of body parts leads to the prospect of exploitation. This is undoubtedly true. But, merely because we face that prospect is no reason *in se* to refuse to recognize property rights as a matter of principle. Exploitation can be guarded against. Indeed, it is naïve to imagine that a black market in body parts does not already exist. It most certainly does.[44] To ignore the reality does not make it go away.

Moreover, this argument is open to significant challenge as an example of undue paternalism. As Andrews has argued in the context of surrogacy, it may be more devaluing to persons not to recognize their worth in monetary terms for the contributions they can make to society from the use of their bodies than it is to protect them from potential predators - provided, always, that the value that they represent is not entirely reducible to those terms.[45]

The exploitation argument also provides an example of an overly pessimistic view of the utility of self-ownership rights. Rather than prejudicing individual interests, the recognition of property rights can bolster the respect that individuals deserve and can at the same time provide a crucial means of ensuring that that respect endures. The wholesale application of a traditional property model to the human body and its parts is not, however, envisioned. This would be inappropriate and unacceptable in many respects. Yet, to the extent that a body property model reflects a desire and need to protect the human personality, certain key features of the language and operation of property rights could serve this end very well.[46]

Researchers might object, however, that it would be impossible to monitor individuals' samples for these would invariably become mixed with others during the research process. But this is not problematic in property terms. The concepts of *commixtion* and *confusion* are well established in property law.[47] Where two separate entities are mixed together and cannot be separated, property in each element ceases and is replaced by common property in the resulting mixture. The new property is owned by each of the interested parties and must be held in trust for the benefit of all. So, if two piles of corn (solids are governed by *commixtion*) or two bottles of wine (liquids are examples of *confusion*) are merged the resulting property is owned in common by the owners of the original elements. So too is could be with genetic samples. Indeed, the notion that property is to be held in trust is entirely apposite in this modern context. The benefits to be derived from the new property should accrue to all of those who have contributed. Alternatively, specification might occur when a new thing has been created without the knowledge or consent of the original owners, for example, where A builds a new house using B's bricks. B cannot claim the return of her bricks in such a case but she is nevertheless entitled to compensation for her loss. So too, once again, it might be with genetic samples. Matters may be more problematic, however, in the context of the ownership of information derived from samples. Information is a difficult concept to fit into the property paradigm, but it is by no means impossible to do so.[48] Collective claims to property in information - such as familial genetic information - might therefore also arise.

#### 4. ACKNOWLEDGEMENT

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- <sup>3</sup> See, European Group on Ethics in Science and New Technologies to the European Commission, *Ethical issues of healthcare in the information society* (Opinion No.13, July 1999), para.2.2.
- <sup>4</sup> Bundesgerichtshof, 9 November 1993, BGHZ, 124, 52.
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